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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 19/04/2002
C(2002) 1571

NOT FOR PUBLICATION

COMMISSION DECISION

of 19/04/2002

amending Decision C(1999) 939 on the marketing authorization for the medicinal product for human use

"Cetrotide - Cetrorelix (as acetate)"

(Text with EEA relevance)

ONLY THE ENGLISH TEXT IS AUTHENTIC.

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"Cetrotide - Cetrorelix (as acetate)"

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], as amended by Commission Regulation (EC) No 649/98[2],

Having regard to Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93[3], as amended by Commission Regulation (EC) No 1069/98[4], and in particular Article 5(2) thereof,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products,

Whereas:

(1) The medicinal product "Cetrotide - Cetrorelix (as acetate)" entered in the Community register of medicinal products under Nos EU/1/99/100/001-003 authorised by Commission Decision C(1999) 939 of 13 April 1999, as amended, complies with the requirements set out in Regulation (EEC) No 2309/93.

(2) Serono Europe Ltd. submitted an application on 19 February 2002 pursuant to Article 4(1) set out in Regulation (EC) No 542/95.

(3) The European Agency for the Evaluation of Medicinal Products delivered a favourable opinion formulated on 15 March 2002 by the Committee for Proprietary Medicinal Products,

(4) Decision C(1999) 939 should therefore be amended accordingly.

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[1] OJ No L 214, 24. 8. 1993, p. 1.
[2] OJ L 88, 24.3.1998, p. 7.
[3] OJ No L 55, 11.3.1995, p. 15
[4] OJ L 153, 27.5.1998, p. 11

(5) In accordance with Article 5(2) of Regulation (EC) No 542/95, this Decision shall take effect retroactively on the 31st day following receipt by the European Agency for the Evaluation of Medicinal Products of the application relating to it.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(1999) 939 is amended as follows:

1. Annex II is replaced by Annex I to this Decision;

2. Annex III B is replaced by Annex II to this Decision.

Article 2

This Decision shall apply from 21 March 2002.

Article 3

This Decision is addressed to Serono Europe Ltd., 56, Marsh Wall, London E14 9TP, United Kingdom.

Done at Brussels, 19/04/2002

For the Commission
Erkki LIIKANEN
Member of the Commission